K091117

SEP 15 2009

510 (k) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

IsoAid, LLC
7824 Clark Moody Blvd., Port Richey, FL 34668
Phone: 727-815-3262
Fax: 727-815-1973

Contact Person: Benjamin Roedell

Date of Summary: April 16, 2009

Trade Name: Advantage-Strand™ / Advantage-Load™ Brachytherapy Kit

Common Name: Brachytherapy Seed Strand in Needle

Classification: Class II (21 CFR 892.5730, Product Code KXK)

Classification Name: Radionuclide Brachytherapy Source

Predicate Devices:

Device	510(k) #
Brachytherapy Strand Device	K040339

Device Description: The IsoAid Brachytherapy Kit is a pre-sterilized kit containing brachytherapy needle and a custom-loaded strand (K013975) of seeds spaced at a precise distance within absorbable suture. The strand is optional, when no strand is requested the seeds and spacers are custom-loaded directly into the needle. A maximum total of 20 seeds and spacers can be loaded into a needle. The spacers (K010621) are made from the same material as the sutures. The stranded Pd-103 (K033770) and I-125 (K011205) implants are placed inside the needle. Bone Wax (K024372) is used at the tip of the need to keep the implants from falling out. The needle is made from 18-gauge stainless steel.

Intended Use: The IsoAid Brachytherapy Kit is intended for the treatment of selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.

Indications for Use: The IsoAid Brachytherapy Kit is indicated for tumors that are localized, unresectable, or have low to moderate radiosensitivity.

Comparison to Predicate Device:

	IsoAid Brachytherapy Kit	Bebig Brachytherapy Strand Device
510(k) Number	K091117	K040339
Indications for Use	Same	
Description	The IsoAid Brachytherapy Kit is a pre-sterilized kit containing brachytherapy needle and a custom-loaded strand (K013975) of seeds spaced at a precise distance within absorbable suture. The strand is optional, when no strand is requested the seeds and spacers are custom-loaded directly into the needle. A maximum total of 20 seeds and spacers can be loaded into a needle. The spacers (K010621) are made from the same material as the sutures. The stranded Pd-103 (K033770) and I-125 (K011205) implants are placed inside the needle. Bone Wax (K024372) is used at the tip of the need to keep the implants from falling out. The needle is made from 18-gauge stainless steel.	The Brachytherapy Strand Device is used for the treatment of localized tumors and is placed into a body cavity or tissue. It consists of a pre-sterilized kit containing a prostate seeding needle and a custom-loaded strand of seeds spaced at a precise distance within absorbable suture. The spacers are made from the same material as the sutures. The customized strand can contain a variable number (1-12) of seeds and/or seeding spacers (maximum 12 components per strand). The stranded Pd-103 and I-125 implants are placed inside the needle. The needle is made from 18 gauge stainless steel.
Radioactive Isotope(s)	Iodine-125 and/or Palladium-103	Same
Application Method	Through an 18 gauge needle	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 15 2009

Mr. Benjamin Roedell
Quality Assurance Manager
IsoAid LLC
7824 Clark Moody Blvd.
PORT RICHEY FL 34668

Re: K091117
Trade/Device Name: Advantage-Strand™ / Advantage-Load™ Brachytherapy Kit
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: August 14, 2009
Received: August 17, 2009

Dear Mr. Roedell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091117

Device Name: Advantage-Strand™ / Advantage-Load™ Brachytherapy Kit

Indications for Use: The IsoAid Brachytherapy Kit is indicated for tumors that are localized, unresectable, or have low to moderate radiosensitivity.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091117